Interview: Daara B. Patel – Secretary-General, Indian Drug Manufacturers Association (IDMA)

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The secretary-general of the Indian Drug Manufacturers Association (IDMA) gives his insight into the current state of the Indian pharma industry, the IDMA's role in raising the quality of Indian-made products, and the country's vital role in the global supply chain.

IDMA is celebrating its 55th anniversary in India and on a personal note it is your 15th anniversary with the company. How has the industry changed within this time frame?

The industry is so much more resilient now than when I began working for IDMA. We have become totally self-reliant. In addition to the fact we are the main producer and supplier of generics, we are also seeing progress across other areas of our business too. One specific area we are witnessing positive growth is in value-added generics and we are on our way to being the world's pharmacy.

There is no country that can manage without Indian medicines. Every developed country has an aging population and as their budgets are shrinking, affordable quality products from India become increasingly appealing.

What is IDMA's current mandate and response to the rapidly evolving national pharmaceutical market? What key milestones and achievements have there been in recent years?

Founded in 1961, IDMA has over 1000 members, made up of large, medium and small national manufacturers spread across the length and breadth of the country. With 20 Committees headed by experts, and very active state boards, IDMA effectively addresses all critically important matters related to wholly Indian Pharmaceuticals. IDMA actively represents Indian Pharma Sector and puts in all round efforts for the growth of this industry in India and to enhance its presence all over the world. Indian National Pharmaceutical Market has been rapidly evolving because of cost efficiency, diversified portfolio, economic drivers & policy support giving it the competitive edge.

IDMA has represented the industry on important legislation such as the Indian Patents Act, 1970, a landmark piece of legislation that gave a huge impetus to the relatively nascent drug industry.

IDMA has been in the forefront, actively supporting Ministry of Health & Family Welfare in compiling and bringing out the Indian Pharmacopoeia and also continues its whole-hearted support to the Indian Pharmacopoeia Commission (IPC) in its activities.

What is IDMA's "Journey towards Pharma Vision 2020 and Beyond" strategy?

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This White Paper submitted by IDMA is based on our suggestions to the Government and deliberations with the Govt. Committees over many years, such as the Parliamentary Standing Committee in 1993, DoP's Working Group for recommendations for 12^{th} 5-year Plan, Task Force for Formulating a Long Term Policy and Strategy for Strengthening Drug Sector in the country formed by Ministry of Health & Family Welfare, the Dr. V. M. Katoch Committe on Bulk Drugs, the DoP Pharma Vision 2020, IDMA Position Paper on APIs etc. The Document points towards a vision of the Indian Pharma Industry as a potential world leader by calling for support from Government in terms of facilitating faster approvals to produce efficacious & affordable drugs, revival of APIs & Intermediates Manufacturers to compete with other countries like China, provisions for Cluster Development, Nutraceuticals, Veterinary Products, Skill Development & Training, IPR, CROs, and by addressing issues related to Indian & Global Regulatory Agencies, Export-Import, Brand Building, Accessibility & Affordability, etc.

IDMA has also extended support and co-operation to the people at the time of natural calamities like floods, earthquakes etc., by providing free medicines.

IDMA keeps members updated on all issues through, regular email circulars and advisories, our website www.idma-assn.org and our weekly IDMA Bulletin.

IDMA regularly organises seminars, training programmes and workshops for the benefit of our members and the pharma industry at large. IDMA has also been organising Pharmaceutical Analysts Convention (PAC) since many years with the active participation of pharmaceutical analysts, academic institutions, national regulatory authorities as well as global regulatory authorities such as USFDA, MHRA, ANVISA, EMA etc.

IDMA recognises excellence & achievement in various field and confers annual Awards such as *IDMA Quality Excellence Awards* in manufacturing of APIs & Formulations, *IDMA Margi Best Patent Award* for best patents granted in India and abroad, *IDMA Research Awards* for original research papers and review articles published in 'Indian Drugs', *IDMA J B Mody Awards* for top-ranking B.Pharm students of Indian Universities, *IDMA-APA Eminent*, *Outstanding and Young Analyst* Awards recognising excellence in QA/QC, and *Corporate Citizen Awards*.

What are the 'hot topics' of most concern to IDMA members? What are the main dynamics occurring in the manufacturing sector in India?

Currently the 'Hot Topic' for our members is the new draft National Pharmaceutical Policy brought out by Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers. If this policy is implemented in current form then it will adversely affect most of the manufacturing companies. In this regard IDMA has made a submission to the ministry against some of the proposed steps like, increasing the span of price control through various direct and indirect measures, making BA/BE tests mandatory for getting drug manufacturing permissions, dual inspections from central & state authorities, enforcing WHO-GMP compliance, implementation of 'one company – one drug – one brand name – one price', restriction of trade margins to stockists, distributors & retailers, stopping 'loan licensing' & 'P2P' manufacturing, enforcing static bar coding, etc.

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What are IDMA's main suggestions to update India's regulatory environment and foster the local and international development of its member companies? With a 100% FDI allowance in pharma sector, what are the opportunities and threats for local companies?

IDMA being the most recognized representative association of Indian Pharma Industry, always submits its views and representations to Indian Regulatory Authority as and when they propose to bring changes in or new regulations.

IDMA has played major role in fostering bilateral agreements with many nations which has helped our members in furthering their domestic and international business. The success of exports from large Indian companies' can be gauged from the fact that top 25 Indian companies export over 60 percent of their total sales, nearly 25 percent of that to US and 20 percent to other developed countries.

What is the significance of the Consolidated FDI Policy (Effective from August 28, 2017)?

Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, Government of India:

As per this policy 100% FDI is allowed through automatic route in Greenfield pharmaceuticals. In Brownfield pharmaceuticals 74% FDI is allowed through automatic route and beyond 74% through GoI approval. FDI in Brownfield pharmaceuticals, under both automatic and government approval routes, is further subject to compliance of certain conditions like, the production level of National List of Essential Medicines (NLEM) drugs, R&D expenditure, transfer of technology.

Foreign MNCs virtually have not shown any interest in developing Greenfield projects in spite of the facility of 100 percent FDI through the automatic route being available for the past 15 years. But there were major acquisitions of Indian companies; the most notable ones are the acquisition of Matrix Labs by Mylan, followed by Daichii Sankyo's acquisition of Ranbaxy, Sanofi Aventis's acquisition of Shanta Biotech and Abbott Labs' acquisition of Piramal Healthcare. Hence it appears that the true purpose of FDI in making India's Pharma Industry grow bigger & faster is not being met.

For US, European and Japanese MNCs, the Indian generic companies are lucrative targets for acquisitions. They can now acquire Indian generic manufacturers and harness their capacities to further their own business interests. One can be sure that such business interests will not include the continued supply of low cost generics. Nor will it include infusion of innovative technologies. Independent and self reliant Indian generic pharma industry is seen as the lifeline for poor patients in different parts of the world. Domination and control of Indian domestic industry by foreign MNCs over a period of time will have many repercussions.

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Sustained price increase, diverting focus to produce & supply high price drugs meant for life-style diseases to rich & developed countries instead of low-cost affordable generics benefiting the majority of the world populations, killing India's generics competition to eliminate threat to Big Pharma, etc., are some of these bad effects. With increased clout in the domestic pharmaceutical industry and in pursuit of its own self-interest in the Indian and export markets, foreign controlled pharmaceuticals can be expected to pursue policies undermining India's commitment to the full use of public health safeguards in its patent law that encourage competition to lower medicine prices. Pharma will lobby for government adoption of measures that go well beyond the World Trade Organization's rules on intellectual property including lowered patent standards, formalization of the moratorium on compulsory licenses, patent term extensions, and new registration-related monopolies including data exclusivity and linking marketing approval of medicines to their patent status.

What is your assessment of growing stringent regulations in foreign markets as well as Trump's government and the impact on generics export from Indian companies? How would you characterize IDMA's efforts to further their Members' Export Record, currently estimated to be 75% of India's total drugs & pharma exports?

The Indian Pharma Industry registered revenue of around USD 33 billion in 2016. Exports form a major part of the industry's turnover and over 50 per cent of the sales comes from exports. Of the total exports of USD 16.8 billion during the year 2016-17, majority of the exports, accounting for 40.6 per cent were to the American continent followed by 19.7 per cent to Europe, 19.1 per cent to Africa and 18.8 per cent within Asia.

At a time when US President Donald Trump has stated that pharmaceutical companies will have to cut "astronomical" drug prices and bring manufacturing back to America in order to create jobs, Indian drug companies are facing strong headwinds due to prompt regulatory action of USFDA, likely imposition of Border Adjustment Tax (BAT) and delay in new drug approvals. The pricing pressure due to increased competition and consolidation in the supply chain, and regulatory scrutiny of the Indian manufacturing units by the USFDA could continue to remain as hurdles for Indian pharma companies. The pharma export volumes from India to US however are expected to rise. This will be backed by about USD 55 billion expected sales gain to generics drugs on account of branded drugs going off patent during 2017-19 which will create an opportunity for CRAMS segment. We expect growth rate for CRAMS (Contract Research and Manufacturing Services) to be higher compared to average growth rate of the industry. These factors are likely to support pharma exports from India.

As informed earlier, IDMA was instrumental in getting through bilateral trade agreements with many countries. India accounts for 20 percent of global exports in generics. India's pharmaceutical exports stood at US$16.8 billion in 2016-17 and are expected to grow by 30 percent over the next three years to reach US$20 billion by 2020.

What is your assessment on the positioning that India should occupy when it comes to pharma manufacturing?

In terms of manufacturing, cost efficiency and competency continue to be India's forte:

- India's cost of production is nearly 33 percent lower than that of the US
- Labour costs are 50–55 percent cheaper than in Western countries
- The cost of setting up a production plant in India is 40 percent lower than in Western countries
- Cost-efficiency continues to create opportunities for Indian companies in emerging markets and Africa
- India has a skilled workforce as well as high managerial and technical competence in comparison to its peers in Asia
- India has the 2nd largest number of USFDA-approved manufacturing plants outside the US
- India has 2,633 FDA-approved drug products
- India has over 546 USFDA-approved company sites, the highest number outside the US

In line with *'Make in India'* initiative by our honourable PM Shri Narendra Modi, in my view, India's pharmaceutical industry must attract FDI inflows from developed countries in setting up Greenfield projects. FDIs for only acquisitions or holding majority stakes in major Indian companies will not benefit much to the domestic industry unless there are substantial R&D investments and technology transfers. India is recognized as *'Pharmacy of the World'* primarily because of formulations supply to more than 200 countries. We must aim to become '*Pharma Manufacturing Hub of the World'*! Associated with the Make in India campaign *'Zero Defect Zero Effect'* is a key phrase, which encourages high-quality manufacturing standards while minimising environmental and ecological impact. Department of Pharmaceuticals, Ministry of Chemicals & Fertilisers, Government of India is actively seeking Indian manufacturers to go for WHO-GMP compliance. It is definitely an important step but needs meticulous implementation keeping a target to have at least 5000 WHO-GMP certified manufacturers by 2020, up from current 1300 WHO-GMP certified units. Thus we can aim to become '***The Pharma Manufacturing Hub of the World***' while continuing to be '***The Pharmacy of the World'***

IDMA is planning to conduct 5 seminars in next 5 months in 5 of the major manufacturing hubs (Baddi, Baroda, Hyderabad, Visakhapatnam & Pondicherry) jointly with Department of Pharmaceuticals on 'Shifting Pharma Industry from Schedule-M to WHO-GMP Compliance'.

IDMA in collaboration with NSF, UK is launching International Education & Certification Program 'Advanced Program in Pharmaceutical Quality Management (APPQM)', encompassing EU, ICH, WHO, US FDA requirements and industry best practices. First batch will commence from September 2017.

What about the country's positioning in terms of R&D?

Our Consolidated FDI Policy (Effective from August 28, 2017), allows 100% FDI through automatic route in Greenfield pharmaceuticals. In Brownfield pharmaceuticals 74% FDI is allowed through automatic route and beyond 74% through GoI approval. FDI in Brownfield pharmaceuticals, under both automatic and government approval routes, is further subject to compliance of certain conditions like, the production level of National List of Essential Medicines (NLEM) drugs, R&D expenditure, transfer of technology. (*R&D expenses being maintained in value terms for 5 years at an absolute quantitative level at the time of induction of FDI. The benchmark for this level would be decided with reference to the highest level of R&D expenses which has been incurred in any of the three financial years immediately preceding the year of induction of FDI.)* This condition needs to be well defined and has to be made more specific and tangible. To encourage R&D in India there has to be a fixed minimum percent (say 10%) of FDI earmarked for R&D investments. This will make India Global Leader in Affordable and Innovative products.

What is your final message for our international audience?

We have discussed so far about the role and functions of IDMA representing India's evergreen pharmaceutical industry which is evolving to become a Global Leader. India is recognised as *'The Pharmacy of the World'* because of its formulations exports to more than 200 countries. Let me enumerate important action points based on the salient features of India's Pharma Industry, which will help us in achieving global supremacy.

> "India's global share of pharmaceuticals is 2.4% by value and 10% by volume. (*This means that by selling the same volume of drugs others would have generated 5 times more value than what India generated!*)"

Global Leader in Generics: India's global share of pharmaceuticals is 2.4% by value and 10% by volume. (*This means that by selling the same volume of drugs others would have generated 5*

times more value than what India generated!) This value and volume gap is mainly because of the low-cost generics which contribute 20% of global exports of generics. To build on this strength, as a market expansion strategy, India should attract 100% FDI through automatic route in Greenfield projects to expand the production capacities.

Value Enhancement by Foraying into Biosimilars Market: Besides building on the traditional generic product pipeline, companies now have to invest in research on complex generics, specialty and differentiated products, and biosimilars. The biosimilars' approval pathways are already in place in US, and EU. (*The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was passed as part of health reform (Affordable Care Act) that President Obama signed into law on March 23, 2010. BPCI Act creates an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA licensed reference product.*) Indian companies can tap this huge high-value market for biosimilars in developed countries, by focusing on biosimilar development which requires huge investments in R&D. (*Often pulled up for spending too little on research and development (R&D), India's biggest pharmaceutical companies now appear to match their global peers in investing for the future. The country's five top drugmakers together spent a record Rs 8,025 crore in R&D in FY17, data from Bloomberg show. The R&D expenses constitute 9% of the cumulative revenues of the companies*). This is possible if we exploit FDIs in Brownfield pharmaceuticals by stringent conditions to spend on R&D.

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